## Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

- 1. (Currently amended) A method of preparing a lyophilized composition comprising:
  - (a) mixing
    - (i) polyoxyethylene (POE) and polyoxypropylene (POP) blockcopolymer;
    - (ii) a polynucleotide;
    - (iii) a cationic surfactant; and
    - (iv) a compound selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, sorbitol, hydrophilic polymers, proteins and mixtures thereof;

at a temperature below the cloud point of said block copolymer to form a mixture; and

- (b) <u>cold filtering the mixture; and</u>
- (c) lyophilizing the mixture.
- 2. (Original) The method of claim 1, wherein said block copolymer is of the general formula:  $HO(C_2H_4O)_x(C_3H_6O)_y(C_2H_4O)_xH$ ; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion ( $C_3H_6O$ ) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion ( $C_2H_4O$ ) is between approximately 1% and 50% by weight.

- 3. (Original) The method of claim 1, wherein said block copolymer is of the general formula: HO  $(C_3H_6O)_y(C_2H_4O)_x(C_3H_6O)_yH$ ; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion  $(C_3H_6O)$  is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion  $(C_2H_4O)$  is between approximately 1% and 50% by weight.
- 4. (Canceled)
- 5. (Original) The method of claim 1, wherein said mixing step (a) is performed at a temperature of about -2°C to about 8°C.
- 6. (Currently amended) The method of claim <u>1</u> [4], wherein said cold filtration step is performed at a temperature of about -2°C to about 8°C.
- 7. (Original) The method of claim 4, wherein said cold filtration step is performed using a filter with a pore size of about 0.01 microns to about 2 microns.
- 8. (Original) The method of claim 2, wherein said block copolymer is CRL-1005.
- 9. (Original) The method of claim 1, wherein the cationic surfactant is selected from the group consisting of benzalkonium chloride (BAK), benethonium chloride, cetrimide, cetylpyridinium chloride, acetyl triethylammonium chloride, (±)-N-(Benzyl)-N,N dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (Bn-DHxRIE),  $(\pm)-N-(2)$ Acetoxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1propanaminium bromide (DHxRIE-OAc),  $(\pm)$ -N-(2-Benzoyloxyethyl)-N,Ndimethyl-2,3-bis(hexyloxy)-1 propanaminium bromide (DHxRIE-OBz) and (±)-N-(3-Acetoxypropyl)-N,N dimethyl-2,3-bis(octyloxy)-1propanaminium bromide (Pr-DOctRIE-OAc).
- 10. (Canceled)
- 11. (Currently amended) The method of claim <u>1</u> [<del>10</del>], wherein said <u>compound</u> amorphous cryoprotectant is sucrose.

- 12. (Canceled)
- 13. (Currently amended) The method of claim 1, wherein said mixture comprises about 1% to about 20% (w/v) of said compound amorphous cryoprotectant or crystalline bulking agent.
- 14. (Original) The method of claim 11, wherein the final concentration of sucrose is about 10% (w/v).
- 15. (Original) The method of claim 1, wherein said mixture additionally comprises a pH stabilizing physiologic buffer.
- 16. (Original) The method of claim 15, wherein said physiologic buffer is selected from the group consisting of: saline, PBS, HEPES, MOPS, BIS-TRIS, sodium phosphate, potassium phosphate, dibasic sodium phosphate (Na<sub>2</sub>HPO<sub>4</sub>), monobasic sodium phosphate (NaH<sub>2</sub>PO<sub>4</sub>), monobasic sodium potassium phosphate (NaKHPO<sub>4</sub>), magnesium phosphate (Mg<sub>3</sub>(PO<sub>4</sub>)<sub>2</sub>·4H<sub>2</sub>O), or D(+)-α-sodium glycerophosphate (HOCH<sub>2</sub>CH(OH)CH<sub>2</sub>OPO<sub>3</sub>Na<sub>2</sub>).
- 17. (Original) The method of claim 16, wherein said physiologic buffer is sodium phosphate.
- 18. (Original) The method of claim 15, wherein the concentration of said physiologic buffer in the mixture is from about 5 mM to about 25 mM.
- 19. (Original) The method of claim 17, wherein said sodium phosphate is at a concentration of about 5 mM to about 25 mM.
- 20. (Original) The method of claim 1, wherein the final concentration of said cationic surfactant present in said mixture is from about 0.01 mM to about 5 mM.
- 21. (Original) The method of claim 1, wherein the final concentration of said block copolymer present in said mixture is from about 1mg/mL to about 50mg/mL.

- 22. (Original) The method of claim 1, wherein the final concentration of said polynucleotide molecules present in said mixture is from about 1ng/mL to about 10mg/mL.
- 23. (Original) A product produced by the process of claim 1.
- 24. (Original) A stable, mono-dispersed product produced by reconstituting the product of claim 23 with an aqueous solution.
- 25. (Original) A product produced by the process of claim 4.
- 26. (Original) A stable, mono-dispersed product produced by reconstituting the product of claim 25 with an aqueous solution.
- 27. (Original) A product produced by the process of claim 15.
- 28. (Original) A stable, mono-dispersed product produced by reconstituting the product of claim 27 with an aqueous solution.
- 29. (Previously presented) The method of claim 9, wherein said cationic surfactant is benethonium chloride.
- 30. (Previously presented) The method of claim 9, wherein said cationic surfactant is cetrimide.
- 31. (Previously presented) The method of claim 9, wherein said cationic surfactant is cetylpyridinium chloride.
- 32. (Previously presented) The method of claim 9, wherein the cationic surfactant is acetyl triethylammonium chloride.
- 33. (Previously presented) The method of claim 9, wherein said cationic surfactant is (±)-N-(Benzyl)-N,N dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (Bn-DHxRIE).

- 34. (Previously presented) The method of claim 9, wherein said cationic surfactant is (±)-N-(2 Acetoxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (DHxRIE-OAc).
- 35. (Previously presented) The method of claim 9, wherein said cationic surfactant is (±)-N-(2-Benzoyloxyethyl)-N,N- dimethyl-2,3-bis(hexyloxy)-1 propanaminium bromide (DHxRIE-OBz).
- 36. (Previously presented) The method of claim 9, wherein said cationic surfactant is (±)-N-(3-Acetoxypropyl)-N,N dimethyl-2,3-bis(octyloxy)-1- propanaminium bromide (Pr-DOctRIE-OAc).
- 37. (Previously presented) The method of claim 1, wherein said compound is one or more monosaccharides.
- 38. (Previously presented) A product produced by the process of claim 37.
- 39. (Previously presented) A stable, mono-dispersed product produced by reconstituting the product of claim 38 with an aqueous solution.
- 40. (Previously presented) The method of claim 1, wherein said compound is one or more disaccharides.
- 41. (Previously presented) A product produced by the process of claim 40.
- 42. (Previously presented) A stable, mono-dispersed product produced by reconstituting the product of claim 41 with an aqueous solution.
- 43. (Previously presented) The method of claim 1, wherein said compound is one or more oligosaccharides.
- 44. (Previously presented) A product produced by the process of claim 43.
- 45. (Previously presented) A stable, mono-dispersed product produced by reconstituting the product of claim 44 with an aqueous solution.